

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/002,540	QUAY, STEVEN	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to the Amendment and RCE filed 14 June 2004 and the telephonic interview of 23 July 2004.
2.  The allowed claim(s) is/are 14-44 and 50-54 (renumbered claims 1-36).
3.  The drawings filed on 13 November 2001 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  
 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
    - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
 Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
 Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
 of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
 Paper No./Mail Date 07232004.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.



Charles A. Marmor, II  
 Primary Examiner  
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**EXAMINER'S AMENDMENT**

1. This Examiner's Amendment is responsive to the Amendment and RCE filed June 14, 2004 and the Terminal Disclaimer filed July 29, 2004. The Examiner acknowledges the cancellation of claims 1-13 and 45-49 and the amendments to claims 14, 15, 22 and 50. Claims 14-44 and 50-54 are pending.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jeffrey J. King on July 23, 2004.

3. The application has been amended as follows:
  - a. Claim 14 has been amended as follows:

14. (Currently Amended) A sample collection device for collecting a biological sample from a mammary organ of a patient, comprising:  
a breast engaging member constructed of a non-porous material sized and dimensioned to receive at least a nipple portion of a breast of said patient and form a suction seal therewith;  
a solid phase sample collection medium in fluid connection with said breast engaging member for receiving a sample of expressed breast fluid; [and]

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vacuum pump means in gaseous connection with said breast engaging member for generating negative pressure through the breast engaging member to facilitate breast fluid expression[, wherein the sample collection device is a hand-held breast pump incorporating said breast engaging member and vacuum pump means in a compact, structurally integrated breast fluid collection apparatus that can be manipulated and operated with one hand, wherein the fluid-retaining well comprises an integral, defined compartment or enclosure within the sample collection housing for receipt of breast fluid and/or constituent samples thereof within a removable fluid reservoir member of the sample collection housing.]; and

a hand-held breast pump incorporating said breast engaging member and vacuum pump means in a compact, structurally integrated breast fluid collection apparatus that can be manipulated and operated with one hand, wherein the hand-held breast pump comprises a fluid-retaining well comprising an integral, defined compartment or enclosure within a sample collection housing for receipt of breast fluid and/or constituent samples thereof within a removable fluid reservoir member of the sample collection housing.

- b. In claim 26, line 1, “primary” has been deleted.
- c. In claim 27, line 4, --sample-- has been inserted following “primary” (second occurrence).
- d. In claim 30, line 2, --member-- has been inserted following “reservoir” (second occurrence).
- e. In claim 43, line 4, --member-- has been inserted following “reservoir”.
- f. Claim 50 has been amended as follows:
  - 50. (Currently Amended) The sample collection device of claim [1] 14, wherein the vacuum pump means comprises a vacuum pump actuating mechanism connected to a vacuum pump housing of the [device] vacuum pump means, wherein the vacuum pump

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actuating mechanism comprises an actuating lever pivotally connected to the vacuum pump housing.

g. In claim 51, line 1, "49" has been changed to --50--.

h. In claim 52, lines 1-2, "claim 1, further comprising a sample collection housing" has been changed to --claim 14--.

4. The following is an examiner's statement of reasons for allowance:

No prior art of record teach or suggest a sample collection device, as recited by Applicant, including a hand-held breast pump incorporating a breast engaging member and a vacuum pump means, a solid phase sample collection medium, and a fluid-retaining well comprising a removable fluid collection reservoir within a sample collection housing

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

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August 6, 2004